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# Incorporating Patient-Reported Outcomes into Shared Decision Making in the Management of Patients with Osteoarthritis of the Knee: A Hybrid Effectiveness-Implementation Study Protocol Paper

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## ABSTRACT

### Introduction

Osteoarthritis (OA) is a major clinical and public health concern. Treatment for knee OA includes nonsurgical treatments and total knee replacement (TKR), which can often alleviate pain and restore physical function, but is expensive and inappropriately performed in up to a third of patients based on guidelines. Patient-reported outcome measures (PROMs) enable evaluating treatment options on outcomes that matter to patients and can thus inform shared decision-making (SDM) between patients and health professionals for preference-sensitive conditions such as knee OA.

### Methods and Analysis

This is a 2-year, 2-site hybrid type 1 study to assess clinical effectiveness and implementation of a machine learning-based patient decision aid (PDA) integrating patient-reported outcomes and clinical variables to guide SDM for patients with knee OA considering TKR. Aim 1 consists of a randomized controlled trial evaluating the clinical effectiveness and impact of the PDA and SDM process on decision quality and treatment options among 200 patients with knee OA at one study site. In Aim 2, using principles of behavior design and intervention mapping, we will implement and evaluate the feasibility and acceptability of the PDA by interviewing 7 health professionals and 25 patients before and 25 after tool implementation at a second study site.

### Ethics and Dissemination

Ethics approval has been obtained from the University of Texas at Austin Institutional Review Board (Protocol Number: 2018-11-0042). This study is registered with Clinicaltrials.gov (NCT04805554). Informed consent will be obtained from all participants. Study results will be disseminated through conference presentations, publications, and professional societies.


## ARTICLE SUMMARY

### Strengths and Limitations

- This study will evaluate a patient-reported outcomes based predictive analytic model in for use in shared decision making in patients with osteoarthritis of the knee considering total knee replacement surgery.
- The study will be conducted in sites in 2 cities with different patient populations and different electronic health records.
- The study design makes innovative use of hybrid effectiveness-implementation methods and principles of behavior design and implementation mapping.
- A limitation of this study is the generalizability of findings to other sites.

### Trial Registration

Registered with clinicaltrials.gov (NCT04805554) on March 18, 2021.

## BACKGROUND

Osteoarthritis (OA) of the knee constitutes a major clinical and public health problem.[1] This common and disabling condition exerts substantial impact on individuals and society at large, accounting for over $27 billion dollars in U.S. health care costs annually.[2] Treatment options for knee OA range from lifestyle changes to pharmacological management to total knee replacement (TKR) surgery. While TKR surgery has a strong track record in alleviating pain and improving functional limitations in individuals with advanced knee OA, there are growing concerns over escalating volume and cost of these procedures. TKR is one of the most common elective surgical procedures: The estimated number of people living in the US in 2010 who have had a TKR was 4.7 million, with widespread variation in rates across states. By 2030, 7.4 million are expected to have knee replacement.[3] Thus, appropriate application of TKR surgery for the right patient at the right time is critical, especially within existing fee-for-service structures that incentivize performing more procedures.[4-8] Notably, up to 33% of TKRs have been shown to be inappropriate based on criteria developed by the American Academy of Orthopaedic Surgeons, resulting in a substantial proportion of patients failing to experience improvement in the outcomes that matter to them. [9,10] Such outcomes can be captured using patient-reported outcome measures (PROMs) – surveys that score aspects of a person's physical, psychological, and social health and wellbeing, directly from their perspective without interpretation by a clinician or researcher.[11] PROMs have now been used extensively in the clinical research arena to evaluate health status and are increasingly being applied in care delivery to monitor health outcomes and provide decision support through shared decision-making (SDM).

### Shared decision making, patient decision aids, and patient-reported outcomes

SDM is a "process of communication in which clinicians and patients work together to make informed health care decisions that align with what matters most to patients."[12] SDM and active patient participation in decision-making can be facilitated by patient decision aids (PDAs) – tools that can help people make informed decisions through the delivery of patient education, knowledge assessment, attainment of patient preferences, and decision support strategies.[13] SDM is most appropriate for "preference-sensitive" conditions, such as OA of the knee, where patients' preferences and values are particularly critical in informing diagnostic and/or treatment decisions. The decision and timing of TKR surgery should not be determined exclusively by objective clinical findings, but rather by patient preferences, values, and goals, making SDM critical in the treatment decision. The importance of the SDM paradigm has been recognized at a national level by the Centers for Medicare & Medicaid Services (CMS), which requires SDM as a condition for coverage for certain preference-sensitive conditions such as lung cancer screening and 2 cardiac procedures.[14] Health care payers are also encouraging use of PROMs; for example, as part of a value-based payment initiative, CMS implemented the Comprehensive Care for Joint Replacement Model, a mandatory bundled payment program for 67 geographic areas that includes a quality incentive for submitting patient-reported outcomes (PROs), as measured by PROMs.[15]

The use of SDM is also gaining traction for clinical decisions regarding TKR surgery vs. non-operative management for patients with OA of the knee. SDM and PRO collection at the point of care have been well studied separately,[16-20] and guidelines on implementing SDM[21] and best practices for collecting and using PROs[22] have been published. Recent work to incorporate PROMs into clinical decision making includes an Agency for Healthcare Research and Quality (AHRQ)-funded project (Gold and Bertini, co-Principal Investigators [PIs]) assessing patient and clinician preferences, understanding, usability, and acceptability of PRO score visualization and presentation in patient portals and electronic health records (EHRs) [23]; a project (Yazdany, PI) creating and evaluating a learning network in public hospital systems to increase the use of PROMs in rheumatoid arthritis and create scalable natural language processing systems to extract PROs from clinical notes [24]; and a project (Solberg, PI) looking at ways to integrate "patient-preferred" hip and knee PRO scores into the EHR for use at point of care.[25]

In the case of TKR, SDM tools and processes are becoming more widely available. For example, an AHRQ-funded study (Tulu, PI) developed an Android smartphone app called TJR Guru for SDM in patients considering total joint replacement (TJR).[26] One study showed that patients randomized to receive decision and communication aids prior to their initial clinic visit with an orthopaedist reported significantly higher rates of reaching informed decisions and higher confidence levels in their decision compared with control-arm patients, and physicians of intervention patients reported higher levels of satisfaction with the patient encounters.[27] Another recent advance in TKR decision making is utilizing machine learning to predict outcomes of TJR surgery.[28]

There is now increasing government-regulated certification and standardization of patient-decision aids (PDAs) and legislation supporting malpractice protection for providers applying SDM using PDAs. Not surprisingly, there has been considerable advancement in PDA development – including an innovative, advanced artificial intelligence-enabled proprietary PDA, named Joint Insights to apply machine learning to PRO and clinical data for patients contemplating TKR vs. non-operative treatment. The full Joint Insights artificial intelligence-enabled PDA includes 3 modules. The education module includes an overview of OA and treatment options, including risks and benefits of each treatment, and a knowledge assessment. The preferences module includes questions about patients' desired levels of pain relief, commitment to postoperative recovery, and willingness to accept surgical risk to identify preferences on a continuum of nonoperative to operative care. Finally, the outcomes module includes a report showing the patient's personalized estimated probabilities of benefits, risks including complications, and likelihood of improvement in joint pain, stiffness, and quality of life following TKR. In a randomized controlled trial, the intervention group utilizing the Joint Insights PDA scored better on measures of decision quality, level of SDM, satisfaction, and physical function without significant differences in patient visit time compared with a control group completing only education and values and preference elicitation questions.[29]

The Joint Insights tool has been implemented at the point of care to guide SDM in patients with knee OA by musculoskeletal providers at UT Health Austin in Austin, Texas (Figure 1).

Still, evidence is lacking on how to make PROMs actionable for patient care and how best to integrate PROMs within existing EHR systems and clinical workflows.[30] The implementation of both PROMs and SDM for use in clinical settings is not without barriers; for example, they require training on proper use and may disrupt clinic flow. How PROs and SDM together affect decision support across different clinical settings, including those that do not routinely capture PROs or institute PDAs in managing knee OA should continue to be explored.

In this study, we are evaluating and implementing a tool to guide SDM in 2 ambulatory orthopaedic surgery practices with different patient populations, levels of experience with PROMs and SDM, and EHR systems. Specifically, the project involves integrating PROs and clinical data into the Joint Insights tool, then using its output in SDM. Knowledge gained will be critical to scaling and spreading use of such tools into SDM among patients with knee OA nationally.

## METHODS AND ANALYSIS

We have designed a 2-year, 2-site study utilizing a hybrid type 1 study design to assess both clinical effectiveness and implementation.[31] Specifically, our 2 aims are:

Aim 1: To evaluate the clinical effectiveness and impact of the PRO-guided predictive analytic Joint Insights tool and process in terms of decision quality and treatment choice for patients with knee OA.

Aim 2: Using principles of behavior design and intervention mapping, to implement and evaluate the feasibility and acceptability of the tool and process in a second clinical setting with a different clinical population, provider group, and EHR.

### Practice settings, patient populations, and use of patient-reported outcomes

*UT Health Austin Musculoskeletal Institute*

The UT Health Austin Musculoskeletal Institute averages about 12 new patients presenting with knee OA per week. Patients are seen by a care team that may include an associate provider (nurse practitioner), physical therapist, social worker, nutritionist, and/or surgeon depending on the patient's needs. Approximately 60% of patients are women, 50% are uninsured but covered by the Medical Access Program (MAP), which provides access to care for uninsured low-income residents of Central Texas, and 32% speak Spanish as their primary language. Musculoskeletal providers collect general and condition-specific PROs from every patient seen in the Musculoskeletal Institute. PROs are collected for clinical purposes via an electronic interface and results are pulled into the EHR (Athena, Watertown, MA).

*UT Heath San Antonio Medical Arts & Research Center*

This academic practice in San Antonio, Texas currently has one orthopaedist who treats the vast majority of patients with knee OA. This provider and a care team comprising resident physicians and an associate provider (nurse practitioner) see 16-26 new patients with knee OA per week, in addition to returning patients with OA. As in Austin, approximately 61% of patients are women, but in contrast to Austin, only 2% are uninsured and 12% report that Spanish is their primary language. UT Health San Antonio Medical Arts & Research Center's ambulatory orthopaedic clinic has not yet implemented collection of PROs from patients. The EHR (Epic, Verona, WI) will be used to distribute PROs to patients through the patient portal (MyChart) and display the PRO scores to clinicians through the EHR's clinician interface; patients not utilizing the patient portal will complete the PROMs on a tablet at the time of their visit, and the output from the tablet will be automatically transmitted into the EHR.

*Joint Insights (Artificial Intelligence-Enabled Shared Decision-Making Tool)*

Joint Insights uses PROMs – specifically, the PROMIS Global-10 mental health subscore[37] and the Knee injury and Osteoarthritis Outcome Score for Joint Replacement (KOOS JR)[38] – along with patient clinical and demographic information (age, sex, race, ethnicity, body mass index, chronic narcotic use, comorbidities, and whether the patient has recently visited an emergency department or been hospitalized), in machine-learning-based predictive analytic models to provide personalized estimates of likely benefit or harm from TKR surgery. The tool is designed to collect PROs or pull in PROs collected through other systems (e.g., an EHR or a third-party PRO platform). It also provides condition-specific education to patients with knee OA and allows a patient to reflect on and document their preferences and goals. The benefit and risk decision making models are trained using data from the OM1 Intelligent Data Cloud, which contains billions of datapoints on hundreds of millions of patients and is drawn from electronic health records, claims, PROs, and other sources. Patient journeys are drawn from this dataset for patients undergoing TKA who have adequate follow-up for the outcome being evaluated. Approximately 675,000 patients' records were used for the original risk model, which continues to be updated. 60.8% of the modeling population (risk model) patients are male, the mean age is 65 years, and the mean body mass index is 31.8 kg/m$^2$

**Research strategy**

*Overview*

This mixed-method study includes a non-blinded randomized controlled trial (RCT) of effectiveness outcomes, plus periodic reflections and semi-structured interviews with providers and patients and review of EHR data to evaluate implementation processes and outcomes (e.g., acceptability). Data will be integrated following recommended principles for mixed-method research to inform ongoing refinements to the predictive analytic Joint Insights tool (via formative evaluation)[29] and plans for scale-up and spread (via intervention mapping).[32, 33]

Aim 1 is slated to be carried out in Year 1 and early in Year 2 in Austin. Each enrolled and consented patient is randomized to 1 of 2 arms: intervention with the full Joint Insights tool (including education on knee OA and treatment options, values and preference elicitation questions, and personalized benefit/risk report) or control receiving only the educational component of the tool and value and preference elicitation questions. The enrollment target is 180, but to account for loss to follow-up, we are enrolling 200 patients. Quantitative outcomes include: 1) decision quality – as captured by the previously validated Decision Process sub-score of the Decision Quality Index (DQI) for knee OA [34] (primary endpoint); and level of SDM from the patient's perspective (CollaboRATE); factors of decision conflict (Decision Conflict Scale 10 [DCS-10]); and decision regret (Decision Regret Scale [DRS]) (secondary endpoints). The DQI, CollaboRATE, and DCS-10 will be assessed at the end of the baseline visit, and the DRS will be assessed at 3-month and 6-month follow-up visits (or by phone or email if patients do not return to the clinic for a visit) (Figure 2), and 2) as an additional endpoint, OA treatment selected (operative vs. non-operative), also assessed at the 3-month and 6-month follow-up.

Aim 2 is being carried out over both years in San Antonio. Year 1 entails preparing UT Health San Antonio's EHR to collect PROMs, preparing the EHR for integration of the predictive analytic tool, assessing baseline feasibility and acceptability, and working with the clinic site to develop an implementation plan. *Baseline interviews* conducted with San Antonio providers and staff inquire about acceptability and feasibility of collecting PROs and using the tool, as well as exploring key factors (barriers and facilitators) impacting motivation and ability to implement the tool and SDM process at the individual and clinic levels. Interview guides are tailored to clinical role (e.g., surgeon, resident, staff) and reflect implementation concepts based in the Consolidated Framework for Implementation Research (CFIR) and behavior design, which theorizes that any given behavior is most likely to manifest when motivation, ability, and a prompt to do the behavior all occur in the same moment. [35] In collaboration with the site's clinical team, we are identifying each step in the workflow necessary to collect PROMs, incorporate the PRO scores and clinical variables into Joint Insights, and conduct SDM for a single patient, and assessing team perspectives on factors impacting the likelihood each step will occur. These data then go into developing a preliminary plan for implementation at the site, which in turn is refined iteratively in collaboration with the clinical team. *Post-implementation interviews* are planned with providers and staff 3 months following tool roll-out to assess reported use of and experiences with the PROMs and Joint Insights tool, adaptations to tool use and workflow integration, and factors impacting likelihood of sustainment.

*Semi-structured interviews* will be conducted with 25 patients prior to implementation in order to assess: priorities and hopes for treatment (e.g., CFIR: Patient Needs and Resources); experience of discussing treatment options with providers; and expectations for next steps in their treatment process. Then, 3 months following implementation, 25 new patients are interviewed to assess experiences with and acceptability of the Joint Insights tool.

Finally, *periodic reflections* will be conducted with members of the Austin and San Antonio implementation teams in order to document implementation processes, adaptations, and contextual factors at each site. Periodic reflections are an established, low-burden method for capturing dynamic factors affecting implementation of health interventions; they will be conducted bi-monthly by telephone or Zoom with each site and the content captured in near-verbatim notes. [36]

**Participants**

*Participant Selection (Aim 1)*

Inclusion criteria:

i) New patients with a presumptive diagnosis of knee OA ages 45-89
ii) Kellgren Lawrence Scale (K-L) joint space narrowing grade of 3 or 4 (moderate to severe OA) and KOOS JR scores of 0-85
iii) Ability to give informed consent for participation in the study
iv) Ability to read text on a tablet in English or Spanish at the 8th-grade reading level

Exclusion criteria:

i) Patients with a prior TKR or prior consultation with another orthopaedic surgeon for TKR
ii) Patients having prior experience with the Joint Insights tool
iii) Patients undergoing consideration for revision joint replacement
iv) Patients seeking care for trauma, psoriatic arthritis, or rheumatoid arthritis
v) Patients with a body mass index less than 20 or greater than 46 kg/m$^2$

*Participant Recruitment (Aim 1)*

Suitable patients for the study are identified during the pre-clinic meeting (huddle). Once the patient has entered the clinic room or private consultation space, they are met by a researcher and invited to participate in the study. If they agree to participate, the researcher obtains informed consent. We will utilize the randomization module of a HIPAA-compliant, research database, Research Electronic Data Capture (REDCap), and the study coordinator will perform the randomization. Due to the nature of the intervention, patients, researchers, and clinicians will not be blinded to treatment arm assignment. Depending on the study arm, patients and providers will either receive, review, and discuss a Joint Insights risk/benefit report (intervention group), or not (control group). Participants who complete follow-up surveys will receive a $25 gift card.

We will stratify patients who enroll in the RCT on 3 variables: ethnicity (Latino/non-Latino), insurance (MAP/non-MAP), and orthopaedist seen (Provider 1 vs. Provider 2). This stratification ensures balance of these 3 variables between intervention and control groups over time and within stratum. Patients from each of resulting 8 strata will be randomized to intervention or control in randomly-sequenced blocks of 4 or 6. Neither provider nor study

participant will know the next allocation in the sequence until the participant is consented and it is time to begin the intervention.

*Participant Recruitment (Aim 2)*

New patients referred for possible TKR surgery at the San Antonio site are contacted by project staff to schedule an interview to be conducted either in-person immediately following their clinic appointment or by Zoom within the subsequent 1-2 days. A research associate obtains informed consent from all willing patients; participants who complete an interview receive a $25 gift card as compensation.

**Statistical Analysis**

*Quantitative analysis (Aim 1)*

For the RCT in Austin, formal comparative analysis will follow the intent-to-treat principle. Primary analysis will compare the intervention and control groups in Austin by using multiple linear regression analysis. The model will include DQI score as the response variable and, as explanatory variables, a binary indicator for the intervention group and 7 binary indicator variables representing the 8 strata in order to reflect the stratified randomization design. Additionally, as a secondary analysis, we will compare treatment decisions between the intervention and control groups by using multiple logistic regression. The model will include the treatment decision as the binary response variable and the same explanatory variables as in the linear regression model. Depending on the uptake of the intervention, additional analyses will follow the “per-protocol” principle wherein the main treatment variable will be whether the Joint Insights tool was actually used.

*Statistical precision and sample size (Aim 1)*

We calculated the sample size for the RCT by treating the Decision Process score of the DQI as continuous. We aimed to detect a treatment effect size (i.e., Cohen’s *D*) as small as 0.5 (consistent with our preliminary data from the first 26 subjects we have studied) with a type I error rate of 0.05 and power of 0.90, assuming equal sample size in intervention and control groups. Given our 8 randomization strata, we estimate a needed sample size of 180 participants, or 90 for each group. With an estimated loss-to-follow-up rate of 10%. our target enrollment for the RCT is 200 participants, or 100 for each arm.

*Qualitative analysis (Aim 2)*

All interviews are audio-recorded for transcription and analysis. Interview data will be analyzed using established processes for rapid qualitative analysis.[39] We will create structured summaries from transcribed recordings to capture CFIR, behavior design, and emerging domains from the provider, staff, and patient perspectives. We will then transpose domain content from summaries into a matrix to allow for structured content comparison across participants and domains (i.e., matrix analysis), an effective method for rapid and rigorous summary of findings to aid in formative and implementation evaluation.[40] In accordance with behavior design and intervention

mapping, we will then identify key factors impacting motivation and ability across each CFIR construct identified, separating out by stakeholder group (clinic staff, providers). For example, Joint Insights-based SDM may be perceived to be relatively advantageous (CFIR domain: Intervention Characteristics) by comparison with previous practice but may also raise concerns about staff burden. We will create a visual map to summarize staff and provider suggestions and concerns across each step of the Joint Insights tool implementation workflow; this map will aid in collaborative implementation planning. Data from periodic reflections will also be analyzed by using rapid qualitative methods in order to assess key events occurring during implementation (e.g., adaptations) and factors impacting implementation (e.g., barriers and facilitators). These findings will be used to support scale-up and spread of Joint Insights-based SDM and the collaboratively developed implementation strategy in future research.

**Patient and Public Involvement**

Patients and industry stakeholders assisted with design and feedback of the Joint Insights PDA tool for readability and usability prior to the start of this research study. Otherwise, no formal patient or public input was involved in design or planning of this study.

## ETHICS AND DISSEMINATION

The University of Texas at Austin Dell Medical School Institutional Review Board (IRB) reviewed and approved this study (protocol number: 2018-11-0042). The University of Texas Health Science Center at San Antonio's IRB has a formal reliance agreement with the University of Texas at Austin IRB. This study was registered at Clinicaltrials.gov (NCT04805554).

Patients and clinic staff are enrolled in this study after providing informed consent. During this study, participants will complete questionnaires related to their decision-making process and experience or will be interviewed formally about their experiences. Data will be kept in strict confidence. No information will be given to anyone without permission from the participant. Confidentiality is assured by use of identification codes, password-protected electronic files on secure servers or hosting applications, and paper files stored under lock and key. The assessments will be conducted in a private setting, through encrypted email, or by telephone.

**Dissemination of Results**

The project will facilitate developing a learning healthcare system. PRO data will be collected electronically and used to inform clinical decision making in real time. We will evaluate PRO data to improve clinical decision making and patient outcomes locally at 2 sites. We will disseminate results through publications, meeting presentations, and professional organizations.

**Data Statement**

The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

**Author contributions**

EL, EF, LU, PJ, JT wrote and edited the manuscript. EF, LU, PJ, KB, PR, and JT made substantial contributions to the conception, rationale, and design of this study. EL, LU, PJ, and KB have contributed to the intervention used in the first aim of the study. EF and JT have significantly contributed to the design and methodology of the second aim of this study. All authors have given approval for this manuscript to be published.

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**Competing interest statement**

Dr. Jayakumar has received personal fees from Johnson and Johnson Medical Devices. Dr. Bozic has received personal fees from the Centers for Medicare & Medicaid Services and Purchaser Business Group on Health; stock options from Carrum Health; and has a leadership role with AAOS. Dr. Bozic has royalty agreements with Wolters Kluwer and Slack Incorporated. The University of Texas at Austin has a royalty agreement with OM1, Inc.

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Figure legends

Figure 1: Process flow of patient-reported outcome measures.

Figure 2: Timeline of primary and secondary outcomes collected for Aim 1 at UT Health Austin

BMI, Body Mass Index; KOOS JR, Knee Osteoarthritis and Injury Outcome Score, Joint Replacement; PROMIS, Patient Reported Outcome Measurement Information System; PHQ, Patient Health Questionnaire; GAD, Generalized Anxiety Disorder Questionnaire; ED, Emergency Department; K-DQI, Knee Decision Quality Instrument; TKR, Total Knee Replacement

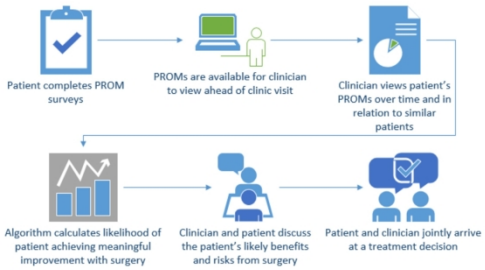


Figure 1: Process flow of patient-reported outcome measures.

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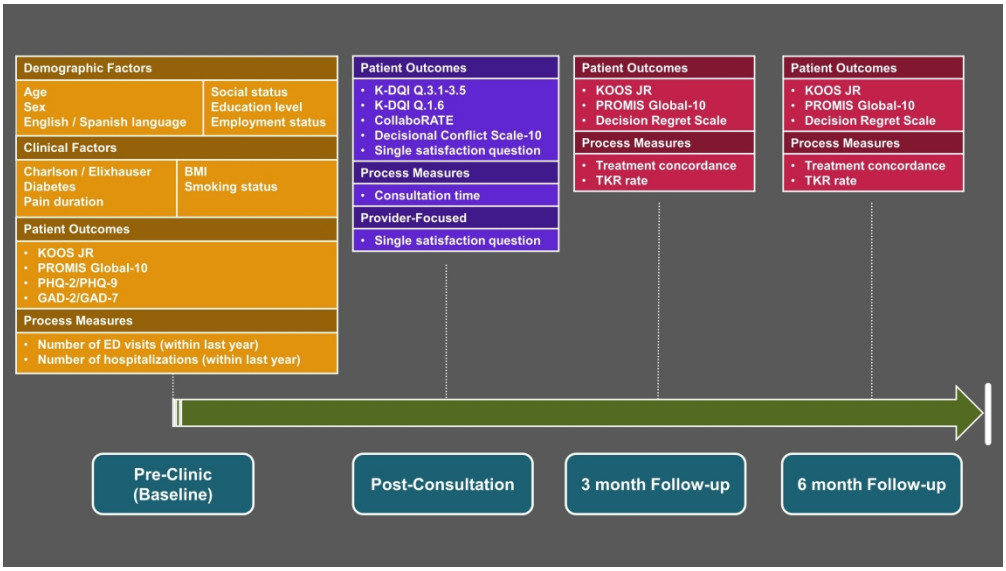


Figure 2: Timeline of primary and secondary outcomes collected for Aim 1 at UT Health Austin

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# Incorporating Patient-Reported Outcomes into Shared Decision Making in the Management of Patients with Osteoarthritis of the Knee: A Hybrid Effectiveness-Implementation Study Protocol

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# Incorporating Patient-Reported Outcomes into Shared Decision Making in the Management of Patients with Osteoarthritis of the Knee: A Hybrid Effectiveness-Implementation Study Protocol

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## ABSTRACT

### Introduction

Osteoarthritis (OA) is a major clinical and public health concern. The primary surgical treatment of knee OA is total knee replacement (TKR), a procedure that aims to alleviate pain and restore physical function. TKA is expensive, however, and, based on professional guidelines, inappropriately performed in up to a third of patients. Patient-reported outcome measures (PROMs) help evaluate treatment options by quantifying health outcomes that matter to patients and can thus inform shared decision-making (SDM) between patients and health professionals.

### Methods and analysis

This is U.S.-based 2-year, 2-site hybrid type 1 study to assess clinical effectiveness and implementation of a machine-learning–based patient decision aid (PDA) integrating patient-reported outcomes and clinical variables to support SDM for patients with knee OA considering TKR. Sub-study 1: At 1 study site, a randomized controlled trial is evaluating the clinical effectiveness of the PDA and SDM process on decision quality as measured after the baseline consultation and treatment choice measured 3- and 6-months after the baseline visit among 200 patients with knee OA. Sub-study 2: At a second study site, a qualitative assessment using principles of behavior design and intervention mapping is evaluating the feasibility and acceptability of the PROMs, PDA, and SDM process by interviewing 7 health professionals and 25 patients before and 25 after PDA implementation.

### Ethics and dissemination

Ethics approval has been obtained from the University of Texas at Austin Institutional Review Board (Protocol Number: 2018-11-0042). Informed consent will be obtained from all participants. Study results will be disseminated through conference presentations, publications, and professional societies.


## ARTICLE SUMMARY

### Strengths and limitations

- A key study design strength is the use of hybrid effectiveness-implementation methods and principles of behavior design and implementation mapping.
- A machine-learning–based tool has a theoretical advantage over a static patient decision aid by continuously refining its prediction algorithms with new input data.
- Another strength is conducting the study at 2 orthopaedic surgery practices with different patient populations, clinical team configurations, and electronic health record systems.
- The primary limitation of this study is the generalizability of findings to other sites.


### Trial registration

Sub-study 1 (protocol version 1.2, dated 2 February 2021) was prospectively registered with Clinicaltrials.gov (NCT04805554) on 18 March 2021.

## INTRODUCTION

Osteoarthritis (OA) of the knee constitutes a major clinical and public health problem.[1] This common and disabling condition has a substantial detrimental impact on affected individuals and society at large, accounting for over $27 billion dollars in U.S. health care costs annually.[2] Treatment options for knee OA range from lifestyle changes to pharmacological management to total knee replacement (TKR) surgery. While TKR has a strong track record in alleviating pain and improving functional limitations in individuals with advanced knee OA, there are growing concerns over the escalating volume and cost of these procedures. TKR is 1 of the most common elective surgical procedures: The estimated number of people living in the U.S. in 2010 who have had a TKR was 4.7 million, with widespread variation in rates across states. By 2030, 7.4 million are expected to have knee replacement.[3] Thus, appropriate application of TKR for the right patient at the right time is critical, especially within existing fee-for-service structures that incentivize performing more procedures.[4–8] Notably, up to 33% of TKRs have been shown to be inappropriate based on criteria developed by the American Academy of Orthopaedic Surgeons, resulting in a substantial proportion of patients failing to experience improvement in the outcomes that matter to them.[9,10] Such outcomes can be captured using patient-reported outcome measures (PROMs) – surveys that score aspects of a person's physical, psychological, and social health and wellbeing, directly from their perspective without interpretation by a clinician or researcher.[11] PROMs have now been used extensively in clinical research to evaluate health status and are increasingly being applied in clinical care to monitor health outcomes and support shared decision-making (SDM).

### Shared decision-making, patient decision aids, and patient-reported outcomes

SDM is a "process of communication in which clinicians and patients work together to make informed health care decisions that align with what matters most to patients."[12] SDM and active patient participation in decision-making can be facilitated by patient decision aids (PDAs) – tools that can help people make informed decisions through patient education, knowledge assessment, elicitation of patient preferences, and decision support.[13] SDM is most appropriate for "preference-sensitive" conditions, such as OA of the knee, where multiple treatment options exist and the patients' preferences and values are critical in making informed treatment choices. Thus, making a decision to undergo TKR should incorporate SDM and understanding of patient preferences, values, and goals, rather than objective clinical findings alone. The importance of SDM has been recognized at a national level by the Centers for Medicare & Medicaid Services (CMS), which ties the concept to coverage of certain other interventions including lung cancer screening and 2 cardiac procedures.[14] CMS and other payers are also promoting the use of PROMs within contemporary alternative payment arrangements such as the Comprehensive Care for Joint Replacement Model – a mandatory bundled payment program for 67 geographic areas that includes a quality incentive for submitting patient-reported outcomes (PROs), as measured by PROMs.[15]

Administering PROMs and performing SDM at the point of care have been well studied separately,[16–20] and guidelines on implementing SDM[21] and best practices for collecting and using PROs[22] have been published extensively. Recent work to incorporate PROMs into clinical decision making includes a project funded by the Agency for Healthcare Research and Quality (AHRQ) assessing patient and clinician preferences, understanding, usability, and acceptability of PRO score visualization and presentation in patient portals and electronic health records (EHRs)[23]; a project creating and evaluating a learning network in public hospital systems to increase the use of PROMs in rheumatoid arthritis and create scalable natural language processing systems to extract PROs from clinical notes[24]; and a project looking at ways to integrate "patient-preferred" hip and knee PRO scores into the EHR for use at the point of care.[25] PDAs are generally static in the sense that their calculations are not updated with new input data. A machine-learning–based tool has a theoretical advantage over a static PDA by continuously refining its prediction algorithms with new input data. Still, studies evaluating the impact of a PRO-driven, machine-learning-technology–enabled PDA in SDM in patients with knee OA considering TKR are lacking.

In this study, we are evaluating and implementing a tool to guide SDM in 2 ambulatory orthopaedic surgery practices with different patient populations, levels of experience with PROMs and SDM, care delivery models, and EHR systems. Specifically, the project involves integrating PROs and clinical data within a machine-learning–based predictive analytic model, then using its output as part of SDM. Knowledge gained will be critical to nationally scaling the use of PROMs and tools (PDAs) for SDM among patients with knee OA considering surgery.

We have designed a 2-year, 2-site study utilizing a hybrid type 1 study design to assess both clinical effectiveness and implementation.[26] Specifically, our 2 aims are:

Sub-study 1: In a randomized controlled trial (RCT) at 1 site, to evaluate the clinical effectiveness of the PRO-guided predictive analytic tool and process in terms of decision quality and treatment choice for patients with knee OA.

Sub-study 2: In a qualitative assessment at the second site, to implement and evaluate the feasibility and acceptability of the tool and SDM process in a clinical setting with a different clinical population, provider group, and EHR by using principles of behavior design and intervention mapping.

## METHODS AND ANALYSIS

### Research strategy

*Overview*

This hybrid effectiveness implementation study includes a non-blinded RCT of effectiveness outcomes at 1 site, plus periodic reflections and semi-structured interviews with providers and patients to evaluate implementation

processes and outcomes (e.g., feasibility and acceptability) at a second site. Data will be integrated following recommended principles for mixed-method research to inform ongoing refinements to the predictive analytic tool (via formative evaluation)[27] and plans for scaling (via intervention mapping).[28,29]

*Joint Insights (artificial-intelligence–enabled SDM tool) and PROMs*

Joint Insights (OM1 Inc., Boston, MA) is a machine-learning–enabled PDA that uses PROMs along with patient clinical and demographic information (age, sex, body mass index, smoking status, comorbidities, and number of times the patient has recently visited an emergency department or been hospitalized) to provide personalized estimates of likely benefit or harm from TKR (Figure 1).[27] The tool is designed to collect PROs or pull in PROs collected through other systems (e.g., an EHR or a third-party PROM platform). It also provides condition-specific education to patients with knee OA and allows a patient to reflect on and document their preferences and goals. Patient journeys are drawn from the OM1 Intelligent Data Cloud for patients undergoing TKR who have adequate follow-up for the outcome being evaluated. Approximately 675,000 patients' records were used for the original risk model, which continues to be updated. In the modeling population (risk model), 60.8% of patients are male, the mean age is 65 years, and the mean body mass index is 31.8 kg/m$^2$. The PROMs used with Joint Insights include the PROMIS Global-10 physical and mental health subscores[30] and the Knee injury and Osteoarthritis Outcome Score for Joint Replacement (KOOS JR)[31]. PROMIS subscores are expressed as t-scores, with 50 representing the population mean; higher scores indicate better physical function (physical function subscore) but worse mental health (mental health subscore). The KOOS JR is a 7-item PROM encompassing questions on function, pain, and stiffness and scored using a t-score from 0 to 100, where 0 represents poorest knee health and 100 represents best knee health.

*Study dates and sites*

This is a 2-year study planned from September 2020 – August 2022. The recruitment start date of this study was 22 February 2021. The PDA has already been integrated into the workflow of the UT Health Austin clinic, where the effectiveness trial (Sub-study 1) is taking place. The study design and choice of different setting (UT Health San Antonio) for the implementation study (Sub-study 2) is intented to elucidate the feasibility and acceptability of implementing the tool into a clinic with a different population; care delivery team having less familiarity with using PROs routinely in practice; and a different EHR system, which automatically uploads PRO scores for the clinician to view at the point of care (Table 1).

Table 1. Comparison of study sites

| | **UT Health Austin** (Sub-study 1) | **UT Health San Antonio** (Sub-study 2) |
|---|---|---|

| | | |
|---|---|---|
| Patient population | 50% MAP patients<br>32% Spanish primary language | 2% uninsured<br>12% Spanish primary language |
| Care team | Orthopaedic surgeons<br>Associate providers (NPs)<br>Social worker, Dietician | Orthopaedic surgeon<br>Associate provider (NP) |
| EHR | Athena | Epic |
| PRO collection methods | Clinect (email pre-visit), tablet-based collection as backup | Epic MyChart portal (pre-visit), tablet-based collection as backup |
| PRO collection uptake | ~100% of patients | Limited |
| PROs collected | General health<br>Mental health (depression, anxiety)<br>Hip- and knee-specific | |

MAP: Medical Access Program (covers health care for otherwise uninsured patients in Travis County); NP: nurse practitioner; EHR: electronic health record; PRO: patient-reported outcome

*Sub-study 1 Overview*

Sub-study 1 is projected to run for year 1 and early in year 2 at the UT Health Austin Musculoskeletal Institute in Austin, Texas. Patients are randomized to 1 of 2 arms: intervention, with the full Joint Insights tool (including education on knee OA and treatment options, preference elicitation questions, and personalized benefit/risk report) or control, receiving only the educational component of the tool and preference elicitation questions. The enrollment target is 180, but to account for loss to follow-up, we are enrolling 200 patients. Quantitative outcomes include the primary endpoint – decision quality – as assessed at the conclusion of the initial consultation by using the previously validated Decision Process sub-score of the Decision Quality Index (DQI) for knee OA [32]; and, as secondary endpoints, level of SDM from the patient's perspective (CollaboRATE); aspects of decision conflict (Decision Conflict Scale 10 [DCS-10]); and decision regret (Decision Regret Scale [DRS]). The DQI, CollaboRATE, and DCS-10 will be assessed at the end of the baseline visit, and the DRS will be assessed at 3-month and 6-month follow-up visits (or by phone or email if patients do not return to the clinic for a visit). As an additional endpoint, we will capture the OA treatment selected (operative vs. non-operative), assessed at the 3-month and 6-month follow-up.

*Sub-study 2 Overview*

Sub-study 2 is being carried out over both years primarily at UT Health San Antonio, San Antonio, Texas. Year 1 has entailed preparing UT Health San Antonio's EHR to collect PROMs, preparing the EHR for integration of the predictive analytic tool, assessing baseline feasibility and acceptability, and working with the clinic site to develop an implementation plan. *Baseline interviews* conducted with San Antonio providers and staff inquired about acceptability and feasibility of collecting PROs and using the tool, as well as exploring key factors (barriers and facilitators) impacting motivation and ability to implement the tool and SDM process at the individual and clinic levels. Interview guides were tailored to clinical role (e.g., surgeon, resident, staff) and reflected implementation concepts based in the Consolidated Framework for Implementation Research (CFIR) and behavior design, which theorizes that any given behavior is most likely to manifest when motivation, ability, and a prompt to carry out the behavior all occur in the same moment (see online appendix).[33] In collaboration with the site's clinical team, we are identifying each step in the workflow necessary to collect PROMs, incorporate the PRO scores and clinical variables into Joint Insights, and conduct an SDM consultation for a single patient, and assessing team perspectives on the barriers and facilitators of each step in this workflow being achieved. These data then go into developing a preliminary plan for implementation at the site, which in turn is refined iteratively in collaboration with the clinical team. *Post-implementation interviews* are planned with providers and staff 3 months following tool roll-out to assess reported use of and experiences with the PROMs and Joint Insights tool, adaptations to tool use and workflow integration, and factors impacting likelihood of sustainment of the process of care.

*Semi-structured interviews* have also been conducted with 25 patients prior to implementing PROMs and Joint Insights in order to assess: priorities and hopes for treatment (e.g., CFIR: Patient Needs and Resources); experience of discussing treatment options with providers; and expectations for next steps in their treatment process. Then, 3 months following implementation, 25 new patients will be interviewed to assess experiences with and acceptability of the Joint Insights tool. A copy of the interview guides can be found in the Supplemental Information file.

Finally, *periodic reflections* are being conducted with members of the Austin and San Antonio implementation teams in order to document implementation processes, adaptations, and contextual factors at each site. Periodic reflections are an established, low-burden method for capturing dynamic factors affecting implementation of health interventions.[34]

**Sub-study 1**

*Practice settings, patient populations, and use of PROs: UT Health Austin Musculoskeletal Institute*

The UT Health Austin Musculoskeletal Institute averages about 12 new patients presenting with knee OA per week. Patients are seen by a care team that may include an associate provider (nurse practitioner), physical therapist, social worker, nutritionist, and/or surgeon depending on the patient's needs. Approximately 60% of

patients are women; 50% are uninsured but covered by the Medical Access Program (MAP), which provides access to care for uninsured low-income residents of Central Texas; and 32% speak Spanish as their primary language. Musculoskeletal providers collect general and condition-specific PROs from every patient seen in the Musculoskeletal Institute (Figure 2). The practice has experience with PROMs, the Joint Insights tool, and SDM. PROs are collected for clinical purposes via an electronic interface and results are pulled into the EHR (Athena, Watertown, MA). Investigators [KJB, PJ] from UT Austin worked with OM1 to co-develop the PDA.

*Participant selection*

Inclusion criteria:

i) New patients with a presumptive diagnosis of knee OA ages 45-89

ii) Kellgren Lawrence Scale (K-L) joint space narrowing grade 3 or 4 (moderate to severe OA) and KOOS JR scores between 0-85

iii) Ability to give informed consent for participation in the study

iv) Ability to read text at the eighth-grade reading level on a tablet in English or Spanish

Exclusion criteria:

i) Patients with a prior TKR or prior consultation with another orthopaedic surgeon for TKR

ii) Patients having prior experience with the Joint Insights tool

iii) Patients undergoing consideration for revision joint replacement

iv) Patients seeking care for trauma, psoriatic arthritis, or rheumatoid arthritis

v) Patients with a body mass index less than 20 kg/m$^2$ or greater than 46 kg/m$^2$

*Participant recruitment and data collection*

The UT Health Austin Musculoskeletal Institute sees a mix of patients seeking care for knee OA comprising a range of pathological severity, and individuals who are referred from primary or specialty care or are self-referred. Suitable patients for the study are identified during the pre-clinic meeting. Once the patient has entered the clinic room or private consultation space, they are met by a researcher and invited to participate in the study. If they agree to participate, the researcher obtains informed consent. We are utilizing the randomization module of REDCap, a HIPAA-compliant, research database. We are stratifying patients who enroll in the RCT on 3 variables: ethnicity (Latino/non-Latino), insurance (MAP/non-MAP), and orthopaedist seen (Provider A [author KJB] vs. Provider B). This stratification ensures balance of these 3 variables between intervention and control groups over time and within stratum. Patients from each of the resulting 8 strata are randomized to intervention or control in randomly sequenced blocks of 4 or 6. Neither provider nor study participant will know the next allocation in the sequence until the participant is consented and it is time to begin the intervention. Due to the nature of the intervention, patients, researchers, and clinicians are not blinded to treatment arm assignment.

Demographic information is collected via tablets after randomization. Next, patients in the intervention group receive a Joint Insights risk/benefit report. Those randomized to the intervention group may review and discuss the Joint Insights report as part of the clinical visit. The control group does not receive the Joint Insights report. Following the completion of the visit, survey instruments are collected for participants in both arms by using REDCap forms on the tablet. At 3 months and 6 months follow-up, participants are given follow-up surveys on REDCap either in person, by email, or by phone. Participants completing follow-up surveys receive a $25 gift card.

*Statistical precision and sample size*

We calculated the sample size for the RCT by treating the Decision Process score of the DQI as continuous. We aimed to detect a treatment effect size (i.e., Cohen's *D*) as small as 0.5 (consistent with preliminary data from the first 26 subjects we have studied) with a type I error rate of 0.05 and power of 0.90, assuming equal sample size in intervention and control groups. Given our 8 randomization strata, we estimate a needed sample size of 180 participants, or 90 for each group. With an estimated loss-to-follow-up rate of 10%, our target enrollment for the RCT is 200 participants, or 100 for each arm.

*Quantitative analysis*

For the RCT in Austin, formal comparative analysis will follow the intent-to-treat principle. Primary analysis will compare the intervention and control groups by using multiple linear regression analysis. The model will include DQI score as the response variable and, as explanatory variables, a binary indicator for the intervention group and 7 binary indicator variables representing the 8 strata in order to reflect the stratified randomization design. Additionally, as a secondary analysis, we will compare treatment decisions between the intervention and control groups by using multiple logistic regression. The model will include the treatment decision as the binary response variable and the same explanatory variables as in the linear regression model. Depending on the uptake of the intervention, additional analyses will follow the per-protocol principle wherein the main treatment variable will be whether the Joint Insights tool was actually used.

For analysis of the 3- and 6-month data, we will fit linear mixed models for continuous outcomes[35] and generalized estimating equations logistic regression models for binary outcomes[36], including indicator variables for time point, for treatment group, and for the interaction between the 2 (yielding treatment effects at 3 months and at 6 months). Owing to the balanced design, it will be possible to fit an unstructured correlation model to eliminate any sensitivity to correlation model misspecification.

**Sub-study 2**

*Practice settings, patient populations, and use of PROs: UT Heath San Antonio Medical Arts & Research Center*

This academic practice in San Antonio currently has 1 orthopaedist who treats the vast majority of patients with knee OA. This provider and a care team comprising resident physicians and an associate provider (nurse practitioner) see 16-26 new patients with knee OA per week, in addition to returning patients with OA. As in Austin, approximately 61% of patients are women, but in contrast to Austin, only 2% are uninsured and 12% report that Spanish is their primary language. The clinic had not implemented PRO collection prior to this study. The clinic uses Epic (Epic, Verona, WI) as its EHR. PROs are collected either through Epic's MyChart patient portal in advance of the patient's appointment or via tablets in the clinic on the day of the appointment. PRO scores are then transmitted to clinicians through the EHR's clinician interface..

*Participant recruitment*

The Medical Arts & Research Center Orthopaedics Clinic in San Antonio sees a mix of patients seeking care for knee OA or considering TKR, and a mix of patients who are referred or self-referred. New patients being seen for possible TKR are contacted by project staff to schedule an interview to be conducted either in-person immediately following their clinic appointment or by Zoom within the subsequent 1-2 days. A research associate obtains informed consent from all willing patients; participants who complete an interview receive a $25 gift card as compensation.

*Sample size calculation*

For staff and provider interviews, we have invited every member of the clinical team to participate in order to have full representation of those involved in implementation. In developing our patient sample, we considered the need to capture heterogeneity in patient demographics, condition severity, need for surgery, health literacy, and preferences for treatment planning, while also acknowledging the relative homogeneity of the patient population being evaluated for knee replacement surgery in a single orthopedic clinic. Following recommendations for ensuring information power, as specified by Malterud and colleagues, we estimated that a sample of 25 patients at each time point would provide adequate information power to represent a broad range of patient experiences and perspectives.

*Qualitative analysis*

All interviews are audio-recorded for transcription and analysis. Interview data will be analyzed using established processes for rapid qualitative analysis.[37] We will create structured summaries from transcribed recordings to capture key domains drawn from CFIR, behavior design, and emerging content reflecting provider, staff, and patient perspectives. We will then transpose domain content from summaries into a matrix to allow for structured content comparison across participants and domains (i.e., matrix analysis), an effective method for rapid and rigorous summary of findings to aid formative and implementation evaluation.[38] In accordance with behavior design and intervention mapping, we will then identify key factors impacting motivation and ability across each CFIR construct identified, separating out by stakeholder group (clinic staff, providers). For example, Joint-

Insights–based SDM may be perceived to be relatively advantageous (CFIR domain: Intervention Characteristics) by comparison with previous practice but may also raise concerns about staff burden. We will create a visual map to summarize staff and provider suggestions and concerns across each step of the Joint Insights tool implementation workflow; this map will aid collaborative implementation planning. Data from periodic reflections will also be analyzed by using rapid qualitative methods in order to assess key events occurring during implementation (e.g., adaptations) and factors impacting implementation (e.g., barriers and facilitators). These findings will be used to support scale-up and spread of Joint-Insights–based SDM and the collaboratively developed implementation strategy in future research, should results of sub-study 1 suggest that the intervention is clinically beneficial.

**Patient and public involvement**

Patients and industry stakeholders assisted with design and feedback of the Joint Insights PDA tool for readability and usability prior to the start of this research study. Specifically, the tool was shown to patients with knee pain in the UT Health Austin Musculoskeletal Institute Lower Extremity Clinic and patients were asked a short set of open-ended questions in response to viewing the risk-benefit calculator in order to assess their understanding of the information presented and their preferences for how the information was displayed. Otherwise, no formal patient or public input was involved in designing or planning this study.

**EXPECTED RESULTS**

Sub-study 1: We expect that patients who use the full Joint Insights tool will have higher decision process scores, reflecting better decision quality, compared with those who receive the education and preferences modules only. We also expect patients in the intervention group to report higher levels of SDM and lower levels of decision conflict and decision regret. We don't expect a difference in rates of treatment selected (operative vs. non-operative) between the 2 groups.

Sub-study 2 is exploratory and therefore has no formal hypotheses.

**ETHICS AND DISSEMINATION**

The University of Texas at Austin Dell Medical School Institutional Review Board (IRB) reviewed and approved this study (protocol number: 2018-11-0042). The University of Texas Health Science Center at San Antonio's IRB has a formal reliance agreement with the University of Texas at Austin IRB. Any modifications to the protocol will be submitted to the UT Austin IRB for approval before implementation.

Patients and clinic staff are enrolled in this study after providing informed consent. During this study, participants complete questionnaires related to their decision-making process and experience or are interviewed formally about their experiences. Data are kept in strict confidence. No information will be given to anyone without

permission from the participant. Confidentiality is assured by use of identification codes, password-protected electronic files on secure servers or hosting applications, and paper files stored under lock and key. The assessments are conducted in a private setting, through encrypted email, or by telephone. Although we don't anticipate any adverse events, any adverse events will be reported to the local IRB.

**Dissemination of results**

The project will facilitate developing a learning healthcare system. PRO data will be collected electronically and used to inform clinical decision-making in real time. We will evaluate PRO data to improve clinical decision-making and patient outcomes locally at 2 sites. We will disseminate results through publications, meeting presentations, and professional organizations.

**Data statement**

The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

**Author contributions**

EL, EF, LU, PJ, JT wrote and edited the manuscript. EF, LU, KB, PR, and JT made substantial contributions to the conception, rationale, and design of this study. EL, LU, PJ, and KB have contributed to the intervention used in the first aim of the study. EF and JT have significantly contributed to the design and methodology of the second aim of this study. All authors have given approval for this manuscript to be published.

**Funding statement**

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**Competing interest statement**

Dr. Jayakumar has received personal fees from Johnson & Johnson Medical Devices. Dr. Bozic has received personal fees from the CMS and Purchaser Business Group on Health; has stock options from Carrum Health; and has a leadership role with the American Academy of Orthopaedic Surgeons. Dr. Bozic has royalty agreements with Wolters Kluwer and Slack Incorporated. Dr. Bozic and Dr. Jayakumar are co-developers of the Joint Insights tool; they have no personal financial interest in the tool. Dr. Tsevat receives royalties from Wolters Kluwer. The University of Texas at Austin has a royalty agreement with OM1, Inc.

**Acknowledgements**

The authors acknowledge OM1 as a co-developer of the Joint Insights tool.

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## Figure legends

Figure 1: Process flow of patient-reported outcome measurements within the clinical pathway

Figure 2: Outcomes collected at UT Health Austin

BMI, Body Mass Index; KOOS JR, Knee Osteoarthritis and Injury Outcome Score, Joint Replacement; PROMIS, Patient-Reported Outcomes Measurement Information System; PHQ, Patient Health Questionnaire; GAD, Generalized Anxiety Disorder questionnaire; ED, Emergency Department; K-DQI, Knee Decision Quality Instrument; TKR, Total Knee Replacement.

The KOOS, JR is a 7-item patient-reported outcome measure of knee joint-related stiffness, pain, and function; interval scores range from 0 to 100, with 0 representing poorest knee health and 100 best knee health. PROMIS Global-10 is a 10-item measure assessing health-related quality of life with items about overall physical and mental health including social connections and physical capabilities. The survey is scored using 2 sub-scores, 1 for physical health and 1 for mental health, wherein specific items are used for a raw score and then converted to a t-score. Population norm t-scores are 50 on each sub-score; higher scores reflect better physical health, but worse mental health. The PHQ is a validated 2- or 9-item survey assessing depressive symptoms and scored categorically as none, mild, moderate, moderately severe, and severe. The 2-item questionnaire is deployed, and if crossing a score threshold, an additional 7 questions are generated. The GAD is a 2- or 7-item survey assessing generalized anxiety disorder and scored categorically as none, mild, moderate, and severe. Similar to the PHQ, if a score threshold is crossed on the 2-item form, an additional 5 questions are generated. The K-DQI is a 16-item survey with 3 specific scores: a total knowledge score, a concordance score, and a decision process score. For the purposes of this study, the 5 questions in the shared decision-making section are used. One point is scored for “yes” or “a lot/some.” These points are summed and then divided by 5, resulting in a score from 0 to 100%, with higher scores indicating a greater level of shared decision-making. The CollaboRATE is a 3-item, 10-point anchor scale measuring the level of shared decision-making in a clinical encounter. It yields a continuous score with a possible range from 0 to 100, where higher scores represent a greater degree of shared decision-making. The DCS is a 10-item survey, with each response value summed, divided by the total item number, and multiplied by 25. The score ranges from 0 to 100, where 0 is no decisional conflict, and 100 is the greatest decisional conflict. Finally, the DRS is a measure that measures distress or remorse after making a healthcare decision. The answer values are summed and converted to a 0-100 scale, where a higher score indicates more regret.

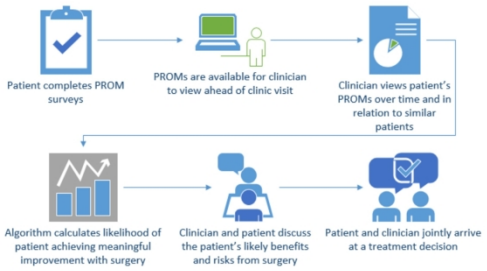


Figure 1: Process flow of patient-reported outcome measures.

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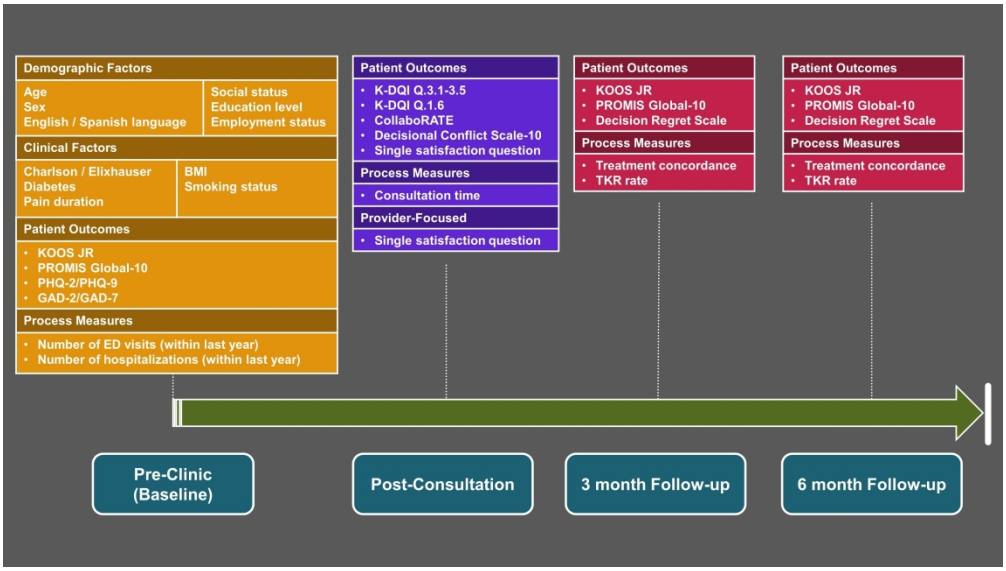


Figure 2: Outcomes collected at UT Health Austin

338x190mm (300 x 300 DPI)

**Supplemental Information**

## Table of Contents

### Informed Consent Documents



### Interview Guides

Consent to Participate in Research

Study Title: Incorporating Patient-Reported Outcomes into Shared Decision Making with Patients with Osteoarthritis of the Knee

Principal Investigator: Kevin Bozic, MD, MBA UT Health Austin Musculoskeletal Institute 1601 Trinity Street, Building A

Study Sponsor: Agency for Healthcare Research and Quality Identification of Investigator and Purpose of Study

You are invited to participate in a research study, called "Incorporating Patient-Reported Outcomes into Shared Decision Making with Patients with Osteoarthritis of the Knee." The study is being done by Dr. Kevin Bozic, Professor of Surgery and Perioperative Care of The University of Texas at Austin, Dell Medical School.

The purpose of this research study is to understand whether giving patients with knee pain information about their likely benefits and risks from surgery improves the quality of their treatment decisions. Your participation in the study may help us understand the usefulness of this educational tool for knee replacement candidates. You are free to contact the researcher at the email address below (under "Contacts") to discuss the study.

If you agree to participate:

You will be randomly selected to either: 1) a group receiving educational materials and personalized estimates of your likely benefit and harm from knee replacement surgery, to 2) a group receiving the educational materials only. There is an equal likelihood (chance) of being selected to each group. This study uses several questionnaires. The questionnaires will take approximately 10 minutes total of your time today. Three (3) months from now and six (6) months from now, we will ask you to fill out a few more questionnaires. If you don't have a follow-up clinic appointment around that time, we will email or call you to complete the surveys on the web or by phone. All information will be securely stored to protect your confidentiality. If you complete both surveys, you will be compensated for your time and participation in this project with a $25 gift card.

Risks/Benefits/Confidentiality of Data

There are no known risks to participating in the study. However, answering the questions might make you feel uncomfortable. If you feel discomfort at any time during this interview, you may stop participating right away. The information gathered in this study will be coded. This means that instead of your name, we will use a participant ID number that is specifically created for this study to link your answers to personal information like phone number and email address. A limited number of research team members will have access to the data. The UT Institutional Review Board (responsible for overseeing ethical conduct of research) may inspect research records and thus access your data. Despite the steps taken to protect your confidentiality, there is a small risk that someone not involved in the study may see the data you provide as part of this study. There will be no costs for participating, nor will you benefit from participating. The information that you provide will not affect your relationship with the University of Texas.

What will happen to the information we collect about you after the study is over?

Information collected as part of the research will not be used or distributed for future research studies. Participation or Withdrawal

Your participation in this study is voluntary. You may decline to answer any question and you have the right to stop participating at any time. If you decide not to participate or withdraw, it will not affect your relationship with The University of Texas in any way. If you do not want to participate, please tell the research assistant.

Contacts

If you have any questions about the study, contact the lead researcher, Dr. Kevin Bozic, by sending an email to kevin.bozic@austin.utexas.edu. This study has been reviewed by The University of Texas at Austin Institutional Review Board and the study number is 2018-11-0042.

Questions about your rights as a research participant.

If you have questions about your rights or are dissatisfied at any time with any part of this study, you can contact, anonymously if you wish, the Institutional Review Board by phone at (512) 232-1543 or email at irb@austin.utexas.edu.

HIPAA Authorization for Research

The purpose of this form is to seek your authorization (permission) for the Principal Investigator listed above and their research team to use and share your individual health information for the above study.

State and federal privacy laws protect your patient information. These laws say that, in most cases, your health care provider can release your identifiable patient information to the research team only if you give permission by signing this form. The research team will use and protect your information as described in the attached Consent Form.

However, once your health information is released it may not be protected by the privacy laws and might be shared with others. If you have questions, ask a member of the research team. You will get a copy of this form.

What organizations' information will you use and share for the study?

Seton/Ascension UT Health

What information will you use and share for the study?

If you give your permission and sign this form, the Principal Investigator and their research team will use and share information from your medical records and other information that can identify you.

For this study the research team will use and share any information from the marked here:

☐ Research Record ☐ Genetic testing information

☐ Entire Medical Record ☐ Information about mental health diagnosis or treatment

☐ History & Physical Exams ☐ Information about drug or alcohol abuse, diagnosis or treatment

☐ Lab & Pathology Results ☐ HIV/AIDS testing information [Texas DSHS' rules require health care providers and laboratories to report cases of HIV and AIDS to local DSHS offices (See https://www.dshs.texas.gov/hivstd/ reporting/).]

☐ Financial records

☒ Other (describe): name, telephone number, email and mailing address, dates (date of birth, date of knee replacement surgery, patient reported outcomes from KOOS JR, DQI, PHQ-2, GAD-2, CollaboRATE, satisfaction and PROMIS-10 surveys, other diagnosed health conditions, smoking status, number of emergency room visits past 12 months, number of overnight hospitalizations past 12 months)

Why will this information be used and shared with others?

To do the research study described in this document

Who is this information shared with?

We may share information that might identify you with:

People who oversee research to make sure it is done safely and correctly (like staff or affiliates from the study sponsor, or the UT Institutional Review Board). For studies or procedures that are related to your medical care, study information may be placed in your medical record. Staff that sees your medical record as part of your care may be aware that you are/were in a research study.

What happens if I say no?

You do not have to sign this form. If you do not, you will not be able to be in the research study. Your decision to not sign this form will not affect any other treatment, health care, enrollment in health plans or eligibility for benefits.

May I change my mind later?

Your permission to use and share information for this study does not have an expiration date unless a time frame is described here: _____

At any time, you can tell us to stop using and sharing health information that identifies you. If you want us to stop, you have to tell us in writing. You can get the researcher's address by calling 512-495-5090.

When we stop, no new health information identifying you will be used or shared. Information that has already been collected may still be used and given to others for limited purposes. For

example, if the law requires it, the sponsor and government agencies may continue to look at your medical records to review the quality or safety of the study.

Giving permission

By signing this form, I agree to participate in this research study and I allow the use and disclosure of my health information for the purposes described above.

Typed Name (First, Last) _____

Signature _____

(Please sign with finger. Click green "Add Signature" to sign.)

Date _____

Time _____

Relationship of Subject or Authorized Representative _____

# Consent to Participate in Research

**Study Title:** Incorporating Patient-Reported Outcomes into Shared Decision Making with Patients with Osteoarthritis of the Knee

**Principal Investigators:** Joel Tsevat, MD, MPH
7411 John Smith Drive
Suite 1050
San Antonio, TX 78229

**Study Sponsor:** Agency for Healthcare Research and Quality

## Key Information

You are invited to participate in a research study. Your participation is voluntary (of your free will).

- Purpose of the research: The purpose of this research study is to understand whether giving patients with knee pain information about their likely benefits and risks from surgery improves the quality of their treatment decisions.
- What is involved: If you choose to participate, you will be interviewed to learn more about your treatment decision experience. This interview will take about 15 minutes and can be scheduled in person or as a virtual interview (through Zoom).
- Risks: There are no known risks to participating in the study. However, answering the questions might make you feel uncomfortable. If you feel discomfort at any time during the interview, you may stop participating right away.
- Benefits: There are no direct benefits for participating in the study. However, we hope the information we learn will be helpful for improving care for patients with knee pain in the future.
- Alternatives to participation: If you decide not to participate, it will not affect your relationship with the University of Texas Health Science Center at San Antonio or UT Physicians in any way.

## Identification of Investigator and Purpose of Study

You are invited to participate in a research study called "Incorporating Patient-Reported Outcomes into Shared Decision Making with Patients with Osteoarthritis of the Knee." The study is being led by Dr. Joel Tsevat, Professor of Medicine, Director, ReACH Center at the University of Texas Health Science Center at San Antonio and Dr. Kevin Bozic, Professor of Surgery and Perioperative Care of The University of Texas at Austin, Dell Medical School.

The purpose of this research study is to understand whether giving patients with knee pain information about their likely benefits and risks from surgery improves the quality of their treatment decisions. Your participation in the study may help us understand the usefulness of this educational tool for knee replacement candidates. You are free to contact the researchers at the email address below (under "Contacts") to discuss the study.

If you agree to participate:

- You will be interviewed to learn more about your treatment decision experience. Please note that your participation in this study involves remote and/or virtual research interactions with our research staff. This interview will take approximately 15 minutes and can be scheduled in-person or through the Zoom web conferencing platform.
- Therefore, privacy and confidentiality is not guaranteed due to the nature of the research environment.
- All information will be securely stored to protect your confidentiality.

- To compensate you for your participation, upon completing the questionnaires and interview, the research team will give you a $25 MasterCard® ClinCard (gift card). Your name, address and date of birth will be shared with a third-party solely for the purposes of processing the compensation. This information will otherwise be kept strictly confidential.

**Risks/Benefits/Confidentiality of Data**

There are no known risks to participating in the study. However, answering the questions might make you feel uncomfortable. If you feel discomfort at any time during this interview, you may stop participating right away. The information gathered in this study will be coded. This means that instead of your name, we will use a participant ID number that is specifically created for this study to link your answers to personal information like phone number and email address. A limited number of research team members will have access to the data. The UT Institutional Review Board (responsible for overseeing ethical conduct of research) may inspect research records and thus access your data. Despite the steps taken to protect your confidentiality, there is a small risk that someone not involved in the study may see the data you provide as part of this study. There will be no costs for participating, nor will you benefit from participating. The information that you provide will not affect your relationship with the University of Texas Health Science Center at San Antonio or UT Physicians.

**What will happen to the information we collect about you after the study is over?**

Information collected as part of the research will not be used or distributed for future research studies.

**Participation or Withdrawal**

Your participation in this study is voluntary. You may decline to answer any question and you have the right to stop participating at any time. If you decide not to participate or to withdraw, it will not affect your relationship with the University of Texas Health Science Center at San Antonio or UT Physicians in any way. If you do not want to participate, please tell the research assistant.

**Contacts**

If you have any questions about the study, contact the lead researcher, Dr. Joel Tsevat, by sending an email to tsevat@uthscsa.edu. This study has been reviewed by The University of Texas at Austin Institutional Review Board and the study number is 2018-11-0042.

**Questions about your rights as a research participant.**

If you have questions about your rights or are dissatisfied at any time with any part of this study, you can contact, anonymously if you wish, the University of Texas Health Science Center at San Antonio, which is the local Institutional Review Board (IRB) committee that reviews research on human subjects. You can contact the IRB by calling 210-567-8250, or by mail to IRB, UTHSCSA, Mail Code 7830, 7703 Floyd Curl Drive, San Antonio, TX 78229-3900.

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## HIPAA Authorization for Research

The purpose of this form is to seek your authorization (permission) for the Principal Investigator listed above and their research team to use and share your individual health information for the above study.

State and federal privacy laws protect your patient information. These laws say that, in most cases, your health care provider can release your identifiable patient information to the research team only if you give permission by signing this form. The research team will use and protect your information as described in the attached Consent Form. However, once your health information is released it may not be

protected by the privacy laws and might be shared with others. If you have questions, ask a member of the research team. You will get a copy of this form. Information we learn about you in this study will be handled in a confidential manner, within the limits of the law. If we publish the results of the study in a scientific journal or book, we will not identify you. The Institutional Review Board and other groups that have the responsibility of monitoring research may want to see study records which identify you as a subject in this study.

Research policies require that private information about you be protected and this is especially true for your health information. However, the law sometimes allows or requires others to see your information. The information given below describes how your privacy and the confidentiality of your research records will be protected in this study.

**What organizations' information will you use and share for the study?**

- The University of Texas Health Science Center at San Antonio/UT Physicians

**What is Protected Health Information (PHI)?**

Protected Health Information is information about a person's health that includes information that would make it possible to figure out who the person is. According to the law, you have the right to decide who can see your protected health information. If you choose to take part in this research study, you will be giving your permission to the investigators and the research study staff (individuals carrying out the study) to see and use your health information for the study. In carrying out this research, the health information we will see and use about you will include:
your medical history and blood work,
information from interviews or from questionnaires
demographic information like your age, marital status, the type of work you do and the years of education you have completed.

We will get this information by looking at your chart at UT Physicians and interviewing you about your experience meeting with your physician.

**What information will you use and share for the study?**

If you give your permission and sign this form, the Principal Investigator and their research team will use and share information from your medical records and other information that can identify you.

For this study the research team will use and share any information from the marked here:

| | |
|---|---|
| ☐ Research Record | ☐ Genetic testing information |
| ☐ Entire Medical Record | ☐ Information about mental health diagnosis or treatment |
| ☐ History & Physical Exams | ☐ Information about drug or alcohol abuse, diagnosis or treatment |
| ☐ Lab & Pathology Results | ☐ HIV/AIDS testing information [Texas DSHS' rules require health care providers and laboratories to report cases of HIV and AIDS to local DSHS offices (See https://www.dshs.texas.gov/hivstd/reporting/).] |
| ☐ Imaging Reports | |
| ☐ Emergency Dept. Record | |
| ☐ Financial records | ☒ Other (describe): *name, telephone number, email and mailing address, dates (date of birth, date of knee replacement surgery)* |

**Why will this information be used and shared with others?**

- To do the research study described in this document

**Who is this information shared with?**

We may share information that might identify you with:

- Members of the local research team
- The sponsor funding the study, Agency for Healthcare Research and Quality, and the entities that they use to monitor, administer, or conduct the research.
- The following collaborators at other institutions that are involved with the study: the University of Texas at Austin, Dell Medical School.
- The Institutional Review Board and the Compliance Office of the University of Texas Health Science Center at San Antonio, and other groups that oversee how research studies are carried out; and
- the Research offices at the University of Texas Health Science Center at San Antonio
- For studies or procedures that are related to your medical care, study information may be placed in your medical record. Staff that sees your medical record as part of your care may be aware that you are/were in a research study.

If you decide to participate in this study, you will be giving your permission for the groups named above, to collect, use and share your health information. If you choose not to let these groups collect, use and share your health information as explained above, you will not be able to participate in this research study.

**How will my information be protected?**

In an effort to protect your privacy, the study staff will use code numbers instead of your name, to identify your health information. Initials and numbers will be used on any photocopies of your study records, and other study materials containing health information that are sent outside the University of Texas Health Science Center at San Antonio or the University of Texas at Austin for review or testing. If the results of this study are reported in medical journals or at meetings, you will not be identified.

**Do you have to allow the use of your health information?**

You do not have to allow (authorize) the researchers and other groups to see and share your health information. If you choose not to let the researchers and other groups use your health information, there will be no penalties, but you will not be allowed to participate in the study.

After you enroll in this study, you may ask the researchers to stop using your health information at any time. However, you must provide this in writing and send your letter to Sarah Lill at 7411 John Smith Drive, Suite 1050, San Antonio, TX 78229-3900. If you tell the researchers to stop using your health information, your participation in the study will end and the study staff will stop collecting new health information from you and about you for this study. However, the study staff will continue to use the health information collected up to the time they receive your letter asking them to stop.

**Can you ask to see the PHI that is collected about you for this study?**

The federal rules say that you can see the health information that we collect about you and use in this study. Contact the study staff if you have a need to review your PHI collected for this study. You will only have access to your PHI until the end of this study.

**What happens if I say no?**

You do not have to sign this form. If you do not, you will not be able to be in the research study. Your decision to not sign this form will not affect any other treatment, health care, enrollment in health plans or eligibility for benefits.

**May I change my mind later?**

Your permission to use and share information for this study does not have an expiration date unless a time frame is described here: _____

At any time, you can tell us to stop using and sharing health information that identifies you. If you want us to stop, you have to tell us in writing. You can get the researcher's address by calling 210-562-5551.

When we stop, no new health information identifying you will be used or shared. Information that has already been collected may still be used and given to others for limited purposes. For example, if the law requires it, the sponsor and government agencies may continue to look at your medical records to review the quality or safety of the study.

**Giving permission**

By signing this form, I agree to allow the use and disclosure of my health information for the purposes described above.

| | | |
|---|---|---|
| Printed Name of Subject | | |
| Signature of Subject or Authorized Representative | Date | Time |
| Relationship of Subject or Authorized Representative | Date | Time |
| Printed Name of Witness | | |
| Signature of Witness | Date | Time |

**Consent to Participate in Research**

| | |
|---|---|
| **Study Title:** | Incorporating Patient-Reported Outcomes into Shared Decision Making with Patients with Osteoarthritis of the Knee |
| **Principal Investigators:** | Joel Tsevat, MD, MPH |
| | 7411 John Smith Drive |
| | Suite 1050 |
| | San Antonio, TX 78229 |
| **Study Sponsor:** | Agency for Healthcare Research and Quality |

**Identification of Investigator and Purpose of Study**

You are invited to participate in a research study called "Incorporating Patient-Reported Outcomes into Shared Decision Making with Patients with Osteoarthritis of the Knee." The study is being led by Dr. Joel Tsevat, Professor of Medicine, Director, ReACH Center at the University of Texas Health Science Center at San Antonio and Dr. Kevin Bozic, Professor of Surgery and Perioperative Care of The University of Texas at Austin, Dell Medical School.

The purpose of this research study is to understand whether giving patients with knee pain information about their likely benefits and risks from surgery improves the quality of their treatment decisions. Your participation in the study will help us to understand more about how we can successfully implement the Joint Insights decision making tool into your clinical practice and may help us understand the usefulness of this educational tool for knee replacement candidates. You are free to contact the researchers at the email address below (under "Contacts") to discuss the study.

If you agree to participate:

- You will be interviewed to learn more about your clinical practice and current shared decision making interactions with patients with Osteoarthritis of the knee. Please note that your participation in this study involves remote and/or virtual research interactions with our research staff. This interview will take approximately an hour and can be scheduled in-person or through the Zoom web conferencing platform.
- Therefore, privacy and confidentiality is not guaranteed due to the nature of the research environment.
- All information will be securely stored to protect your confidentiality.

**Risks/Benefits/Confidentiality of Data**

There are no known risks to participating in the study. However, answering the questions might make you feel uncomfortable. If you feel discomfort at any time during this interview, you may stop participating right away. The information gathered in this study will be coded. This means that instead of your name, we will use a participant ID number that is specifically created for this study to link your answers to personal information like phone number and email address. A limited number of research team members will have access to the data. The UT Institutional Review Board (responsible for overseeing ethical conduct of research) may inspect research records and thus access your data. Despite the steps taken to protect your confidentiality, there is a small risk that someone not involved in the study may see the data you provide as part of this study. There will be no costs for participating, nor will you benefit from participating. The information that you provide will not affect your relationship with the University of Texas Health Science Center at San Antonio or UT Physicians.

**What will happen to the information we collect about you after the study is over?**

Information collected as part of the research will not be used or distributed for future research studies.

**Participation or Withdrawal**

Your participation in this study is voluntary. You may decline to answer any question and you have the right to stop participating at any time. If you decide not to participate or to withdraw, it will not affect your relationship with the University of Texas Health Science Center at San Antonio or UT Physicians in any way. If you do not want to participate, please tell the research assistant.

**Contacts**

If you have any questions about the study, contact the lead researcher, Dr. Joel Tsevat, by sending an email to tsevat@uthscsa.edu. This study has been reviewed by The University of Texas at Austin Institutional Review Board and the study number is 2018-11-0042.

**Questions about your rights as a research participant.**

If you have questions about your rights or are dissatisfied at any time with any part of this study, you can contact, anonymously if you wish, the Institutional Review Board by phone at (512) 471-8871 or email at orsc@uts.cc.utexas.edu.

The University of Texas Health Science Center at San Antonio is the local Institutional Review Board committee that reviews research on human subjects (Institutional Review Board) and can also answer any questions about your rights as a research subject, and take any concerns, comments or complaints you may wish to offer. You can contact the IRB by calling 210-567-8250, or by mail to IRB, UTHSCSA, Mail Code 7830, 7703 Floyd Curl Drive, San Antonio, TX 78229-3900.

Printed Name of Subject

Signature of Subject or Authorized Representative Date Time

Relationship of Subject or Authorized Representative Date Time

Printed Name of Witness

Signature of Witness Date Time

**Patient Interview (Baseline and Post-Implementation)**

Good Day Mr./Ms._____

You have been selected to participate in a research study called "Incorporating Patient-Reported Outcomes into Shared Decision Making with Patients with Osteoarthritis of the Knee." You were identified as a potential participant in this study because you are a patient of _____ and you have arthritis of the knee.

The purpose of this research study is to understand whether giving patients with knee pain information about their likely benefits and risks from surgery improves the quality of their treatment decisions. Your participation in the study may help us improve care in this clinic.

If you agree to participate:

- You will be interviewed to learn more about your treatment decision experience.
- This interview will take approximately 15 minutes and can be scheduled in-person (right now if you are available) or through the Zoom web conferencing platform.
- Therefore, privacy and confidentiality are not guaranteed due to the nature of the research environment.
- All information will be securely stored to protect your confidentiality.
- Your information will not be shared with your providers or anyone in this clinic
- To compensate you for your participation, upon completing the interview, the research team will give you a $25 MasterCard® ClinCard (gift card). Your name, address and date of birth will be shared with a third-party solely for the purposes of processing the compensation. This information will otherwise be kept strictly confidential.

*Patient History, Functional Impact, and Concerns*

1. Please tell me a little bit about your knee. How long has it been bothering you, and how does it impact you?

2. Have you ever had treatment for your arthritis before? [If yes:] can you tell me more about that? What prompted you to get treatment? How did that turn out?

3. What are your priorities in coming to this clinic? Why are you here seeing _____ for your knee? What are you hoping for from treatment? (What are you hoping this going to do for you?)

*Patient Experiences of Care, Communication, and Decision-Making*

4. How did you feel about your appointment (with the orthopedist)?

5. How did the appointment go? Can you walk me through what happened during your appointment?
   - What are some of the things you talked about?
   - What sort of questions did your provider ask?

6. Do you have a plan now for treatment? Can you tell me a little bit about that?

7. Can you walk me through how you and your provider(s) came to that treatment plan?
    - Did you discuss different treatment options?
    - What treatment did you decide on? Why was this plan selected?
    - Was there information you found helpful in making the treatment plan?
    - Was there anything you found difficult or confusing about making the treatment plan?

8. Did you feel like all of your questions were answered?
    - Were there questions you would have liked to ask but didn't? If so, what were they?

*Patient Understanding and Expectations for Next Steps in their Treatment Process*

9. Can you tell me a little bit about what happens next with your treatment?

10. How do you feel about your treatment plan overall?

11. How did you feel in general about the care you received? Were there things that could have been better?

12. Is there anything additional you think we should know or you'd like to tell me?

Thank you so much for your time and input!

**Baseline Provider Interview**

The purpose of this research study is to understand whether giving patients with knee pain information about their likely benefits and risks from surgery improves the quality of their treatment decisions. Your participation in the study is voluntary and will help us to understand more about how we can successfully implement the Joint Insights decision making tool into your clinical practice and may help us understand the usefulness of this educational tool for knee replacement candidates. You are free to contact the researchers at the e-mail address provided on the consent document.

You are being interviewed to learn more about your clinical practice and current shared decision making interactions with patients with osteoarthritis (OA) of the knee. Since this interview is taking place over an online platform, your privacy and confidentiality cannot be fully guaranteed due to the nature of the research environment. All information collected in this interview will be securely stored to protect your confidentiality.

We are recording interviews to allow for learning and analysis – do you mind if we record? [If yes, start the recording and ask again for verbal consent once recording has begun: "We have started the recording – do you mind confirming that you are ok with us recording?" If no, say, "Ok. We will be taking notes throughout the interview."]

Professional Background/Baseline Behaviors

1. Can you first tell me a little bit about your professional experience and training?

2. How long have you been at this facility and what is your role here? [Professional role]

3. Please briefly describe the population of patients you see in this clinic.

4. Now I'd like to ask specifically about how you would normally go about identifying the appropriate treatment for a patient with knee OA in this clinic. What would that process ordinarily look like? [Baseline behaviors]

    - Probe if needed: Do patient history, pain status, or other evaluations play a role in your decision making?

    - What strategies or criteria do you use for identifying an appropriate treatment? How do you evaluate whether patients may be more likely to benefit from or be at risk of negative outcomes from a particular treatment?

    - What information is typically included in the chart, and how do you reference that information as part of your treatment planning and discussions with patients?

5. How do you generally approach treatment planning with your patients?

6. How do you talk with your patients about the available treatments for knee OA?

General PRO Awareness/Perceptions

7. How familiar are you with the idea of patient-reported outcomes or PROs? What do you think about them? Have you ever worked with them?

    Probes:

- Some examples might include the PHQ-9, KOOS Jr, or PROMIS Global. Are there any measures like this that you routinely use for patients with knee OA?

- [If yes:] What role do these measures play in your evaluation and treatment planning process for patients with knee OA?

8. Has your clinic tried to implement PROs in the past? If so, how did that go?

9. Do you feel like your clinic is able to integrate PROs as they become available?

Joint Insights: Perceived Feasibility and Acceptability, Contextual Readiness, Barriers/Facilitators

As you know, we are working toward implementing a tool called **Joint Insights** into your clinic. Joint Insights is a predictive analytic tool co-developed by OM1 and UT Health Austin that uses PRO scores (KOOS Jr and PROMIS Global) and clinical data to estimate the likelihood of a successful clinical outcome with total knee replacement. It provides individualized estimates at the point of care of the potential risk and benefits of treatment modalities.

10. How do you feel about the idea of adding the Joint Insights tool into your clinic? Are there things that make you feel motivated to do this? Are there concerns that make you feel less motivated? [motivation and barriers]

    - What do you think the benefits of this tool in your clinic would be?

    - What concerns do you have about use of this tool in your setting?

    - Do you think this tool will help meet the needs of your patients? Why or why not?

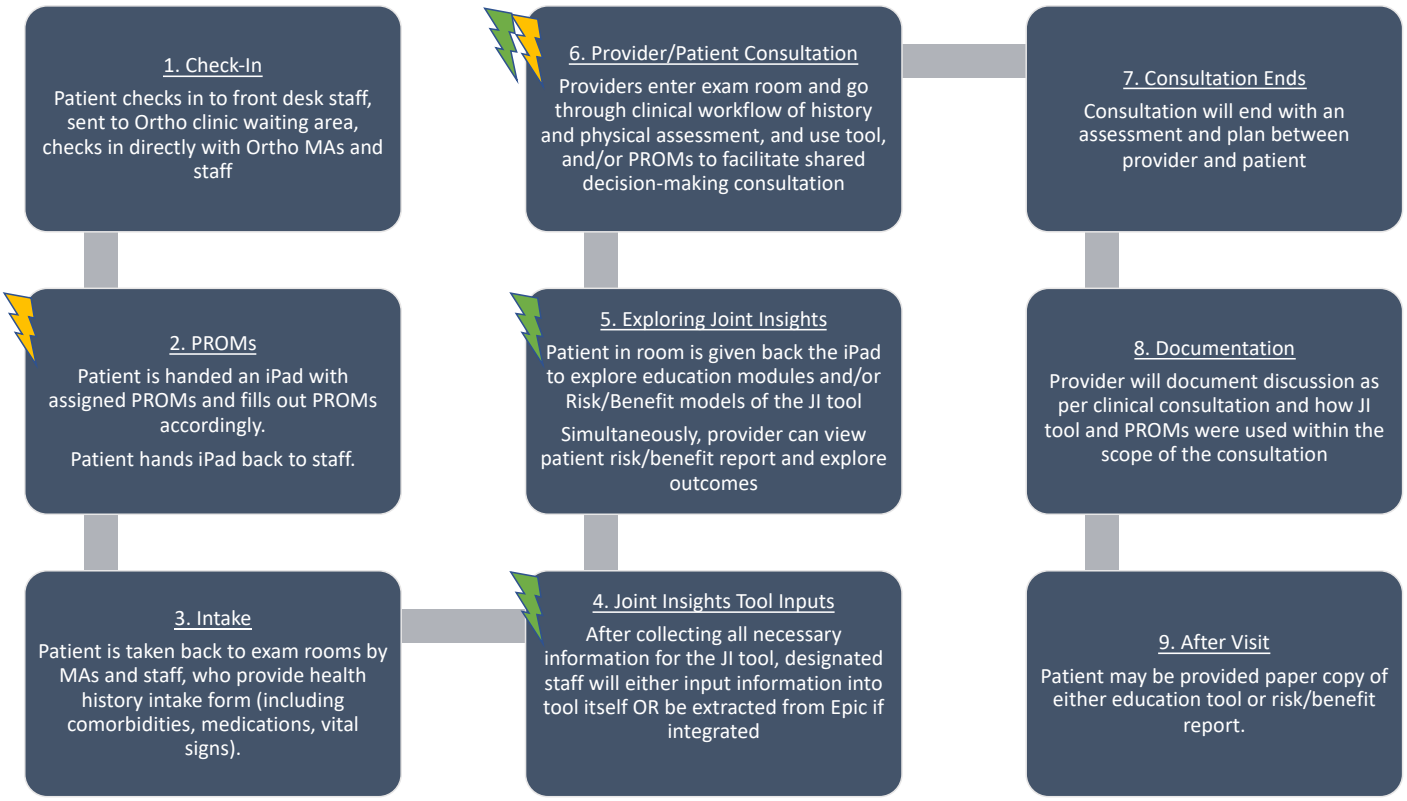
11. To what degree do you feel able to integrate the Joint Insights tool into your routine practice? Do you feel like this is something you can get yourself to do? Why or why not? [ability and barriers]

12. Thinking a little more broadly, to what degree do you feel like your clinic will be able to integrate the Joint Insights tool into routine practice? Do you feel like this will work in your clinic? Why or why not? [ability and barriers]

    - Do you think other providers in this setting will use this tool in their routine practice?

    - What do you think might be potential problems trying to implementing this tool in your clinic?

13. Now I'd like to think together in a little bit more detail about workflow. Let's walk together through the diagram below. As we walk through, I'd love to hear your thoughts on how well you think this will work in your clinic, and what might make this tool easier to use or incorporate into workflow.






Recommendations for Tailoring and Implementation [Note: revisit diagram as needed.]

13. Are there prompts that could be inserted into the workflow (or that already exist) to aid in remembering to use the tool?

14. Do you feel clear about how you'll talk to patients using the PRO information gathered by the tool? What are your thoughts on including this as part of your conversation with them?

15. Two of the options for integrating patient reports into the workflow include printing out a paper report for each patient on their PRO measures and individualized estimates of risks and benefits, or have that information integrated into EPIC. Which of those options do you think would be more helpful or a better fit for your clinic?

16. Are there other data you'd like to see captured for accurate results or clinic needs?

14. Our goal from here is to take this information and develop a plan for implementing the tool. We'll continue to be in touch with you about building out that plan and other progress. Do you have any final thoughts on the tool or what would be most helpful to you and your team going forward?

Thank you for your time!

**Post-implementation Provider Interview**

The purpose of this research study is to understand whether giving patients with knee pain information about their likely benefits and risks from surgery improves the quality of their treatment decisions. Your participation in the study is voluntary and will help us to understand more about how we can successfully implement the Joint Insights decision-making tool into your clinical practice and may help us understand the usefulness of this educational tool for knee replacement candidates. You are free to contact the researchers at the e-mail address provided on the consent document.

You are being interviewed to learn more about your clinical practice and current shared decision-making interactions with patients with osteoarthritis (OA) of the knee. Since this interview is taking place over an online platform, your privacy and confidentiality cannot be fully guaranteed due to the nature of the research environment. All information collected in this interview will be securely stored to protect your confidentiality.

We are recording interviews to allow for learning and analysis – do you mind if we record? [If the patient agrees, start the recording and ask again for verbal consent once recording has begun: "We have started the recording – do you mind confirming that you are ok with us recording?" If the patient does not want the interview to be recorded, say, "Ok. We will be taking notes throughout the interview."]

Professional Background/Post-Implementation Behaviors

1. [If new staff since baseline:] Can you first tell me a little bit about your professional experience and training?

2. [If new staff since baseline:] How long have you been at this facility and what is your role here? [Professional role]

3. Do you mind if we start by walking through the normal check-in, assessment and treatment planning process for a patient with knee OA being evaluated for surgery in this clinic? What does that process look like? [Post-implementation behaviors]

    - Probe if needed: What kind of evaluations (e.g., patient history, pain status) play a role in your decision making?
    - How do you generally approach treatment planning with your patients?
    - How do you talk with your patients about the available treatments for knee OA?

Experience with PROM/Joint Insight Implementation

4. Can you tell me a little bit about the effort to implement patient-reported outcome measures (PROMs) in the clinic? How has that process been going?

    - Are patients completing PROMs? How frequently? What have been some of the challenges in getting patient-reported outcomes (PROs) integrated into the clinic?
    - How are patients completing the PROMs (e.g., in MyChart, on paper, on tablet)? How well is that working?

- [If PROMs being implemented:] What have been some of the key ingredients in getting PROMs integrated as part of the clinic's workflow?
- What additional supports would be valuable in supporting implementation of PROMs for patients?
- Do you have recommendations for other clinics trying to make PROMs part of their routine workflow?

5. [If PROMs implemented:] Once a patient completes the PROMs, how are those data made available to the clinical team (e.g., entered into record by staff member, forms left in exam room, etc.)?
   - How well is that process working? What have been some of the challenges?
   - Are there improvements that you would like to see in how the process works?

6. [If PROMs implemented:] Do you feel like having PROMs available has resulted in any change to the evaluation and treatment planning process for patients with knee OA in your clinic at all? [If yes:] How so? [If no:] Can you say a little bit more about that?

   - [If applicable:] Are there particular measures (e.g., KOOS Jr, PROMIS Global) that are more or less likely to impact treatment planning or the conversation with patients? How so?

7. Can you tell me a little bit about the effort to implement Joint Insights in the clinic? [If a reminder is needed: Joint Insights is a predictive analytic tool co-developed by OM1 and UT Health Austin that uses PRO scores (KOOS Jr and PROMIS Global) and clinical data to estimate the likelihood of a successful clinical outcome with total knee replacement. It provides individualized estimates at the point of care of the potential risk and benefits of treatment modalities.] How has that process been going?

   - Is the Joint Insights tool being used with patients being assessed for total knee replacement at this clinic? How frequently? What have been some of the challenges in getting Joint Insights up and running in the clinic?
   - How are patient data being entered into Joint Insights? How well is that working?
   - [If Joint Insights is being implemented:] What have been some of the key ingredients in getting Joint Insights integrated as part of the clinic's workflow?
   - What additional supports would be valuable in supporting implementation of Joint Insights?
   - Do you have recommendations for other clinics trying to make Joint Insights part of their routine workflow?

8. [If Joint Insights implemented:] Do you feel like having Joint Insights available has resulted in any change to the evaluation and treatment planning process for patients with knee OA in your clinic at all? [If yes:] How so? [If no:] Can you say a little bit more about that?

   - [If applicable:] Are there particular elements of the Joint Insights tool that are more or less likely to impact treatment planning or the conversation with patients? How so?

9. [If Joint Insights implemented:] How satisfied do you feel with the Joint Insights tool at this point? Can you say a little more about what you are appreciating or not appreciating about the tool?

10. [If Joint Insights implemented:] Have you gotten any sense of what patients think about the Joint Insights tool?
    1. Have you heard any negative feedback about the tool from patients? What have you heard?
    2. Have you heard any positive feedback about the tool from patients?

11. What has been the response, if any, to the Joint Insights tool from other providers and staff in the clinic? Has there been negative or positive feedback about the tool or its implementation?

12. Looking ahead, to what degree do you feel that your clinic is likely to continue using PROMs and/or Joint Insights *[note to interviewer: only ask about sustaining program elements that were implemented]* as part of your practice? Do you feel like this will be sustainable in your clinic? Why or why not? [ability and barriers]

    - Do you think other providers in this setting will adopt/continue use of this tool in their routine practice?

    - What do you think might be potential problems trying to keep PROMs and/or Joint Insights going as part of routine practice in your clinic?

    - Are there additional resources or supports that would be helpful in trying to continue use of the PROMs or Joint Insights in your clinic?

13. Thinking about working together with the study/implementation team to get PROMs and Joint Insights up and running in the clinic, how well did that process work?
    0. Were there things that would have made that progress work better or be more efficient?
    1. What recommendations would you have for the team about improving how they support clinics in implementing PROMs/Joint Insights in working with future sites? Are there things the team could do better next time?

14. Are there any other thoughts or reflections you would like to share regarding these tools or the implementation process?

Thank you for your time!

SPIRIT
STANDARD PROTOCOL ITEMS: RECOMMENDATIONS FOR INTERVENTIONAL TRIALS

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

| Manuscript Page No. / Line No. | Section/item | ItemNo | Description |
|---|---|---|---|
| **Administrative information** | | | |
| 1 / 1-2 | Title | 1 | Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym |
| 3 / 81-82 | Trial registration | 2a | Trial identifier and registry name. If not yet registered, name of intended registry |
| | | 2b | All items from the World Health Organization Trial Registration Data Set |
| 3 / 81 | Protocol version | 3 | Date and version identifier |
| 18 / 599-603 | Funding | 4 | Sources and types of financial, material, and other support |
| 18 / 594-597 | Roles and responsibilities | 5a | Names, affiliations, and roles of protocol contributors |
| | | 5b | Name and contact information for the trial sponsor |
| | | 5c | Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities |
| | | 5d | Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee) |
| | **Introduction** | | |

| | | | |
|---|---|---|---|
| 3-6 / 85-185 | Background and rationale | 6a | Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention |
| | | 6b | Explanation for choice of comparators |
| 6 / 176-185 | Objectives | 7 | Specific objectives or hypotheses |
| 5 / 176-177 | Trial design | 8 | Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory) |
| | **Methods: Participants, interventions, and outcomes** | | |
| 9 / 291-302, 12 / 383-394 | Study setting | 9 | Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained |
| 10 / 305-317, 15 / 498-503 | Eligibility criteria | 10 | Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists) |
| 8-9 / 235-274 | Interventions | 11a | Interventions for each group with sufficient detail to allow replication, including how and when they will be administered |
| | | 11b | Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease) |
| | | 11c | Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests) |
| | | 11d | Relevant concomitant care and interventions that are permitted or prohibited during the trial |

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| 8 / 240-248 | Outcomes | 12 | Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended |
| 8 / 240-248, Figure 2, 9 / 270-274 | Participant timeline | 13 | Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure) |
| 11 / 350-355, 16 / 526-533 | Sample size | 14 | Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations |
| 10 / 320-332, 15 / 498-503 | Recruitment | 15 | Strategies for achieving adequate participant enrolment to reach target sample size |
| | **Methods: Assignment of interventions (for controlled trials)** | | |
| | Allocation: | | |
| 10 / 324-332 | Sequence generation | 16a | Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions |
| 10 / 324-332 | Allocation concealment mechanism | 16b | Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned |
| 10 / 322-325 | Implementation | 16c | Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions |
| 10 / 331-332 | Blinding (masking) | 17a | Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how |

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| | | 17b | If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial |
| | **Methods: Data collection, management, and analysis** | | |
| 8 / 240-248, 254-279, 10 / 334-339 | Data collection methods | 18a | Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol |
| | | 18b | Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols |
| 17 / 580-583 | Data management | 19 | Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol |
| 11 / 358-372 | Statistical methods | 20a | Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol |
| | | 20b | Methods for any additional analyses (eg, subgroup and adjusted analyses) |
| | | 20c | Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation) |
| | **Methods: Monitoring** | | |
| N/A: low risk study | Data monitoring | 21a | Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed |

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| | | 21b | Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial |
| 17 / 583-584 | Harms | 22 | Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct |
| N/A | Auditing | 23 | Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor |
| | **Ethics and dissemination** | | |
| 17 / 572-575 | Research ethics approval | 24 | Plans for seeking research ethics committee/institutional review board (REC/IRB) approval |
| 17 / 574-575 | Protocol amendments | 25 | Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators) |
| 10 / 322-324, 15 / 499-503 | Consent or assent | 26a | Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32) |
| | | 26b | Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable |
| 17 / 580-582 | Confidentiality | 27 | How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial |
| 18 / 605-610 | Declaration of interests | 28 | Financial and other competing interests for principal investigators for the overall trial and each study site |
| 18 / 591-592 | Access to data | 29 | Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators |
| N/A | Ancillary and post-trial care | 30 | Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation |

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| 17 / 586-589 | Dissemination policy | 31a | Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions |
| | | 31b | Authorship eligibility guidelines and any intended use of professional writers |
| | | 31c | Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code |
| | **Appendices** | | |
| SI / 2-12 | Informed consent materials | 32 | Model consent form and other related documentation given to participants and authorised surrogates |
| N/A | Biological specimens | 33 | Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable |

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.